

Session 1: Implementation of the HMA/EMA Big Data Task Force priority recommendations

Some milestones already achieved are particularly relevant from an HTA perspective :

- The continuous expansion of DARWIN EU capacity to deliver RWD studies,
- The launch of the EMA-HMA catalogue of data sources and non-interventional studies.

Priorities for the next years should be :

- **To support the use of existing data sources by:**
 - the development of disease registries and network of registries (e.g. ERNs), that collect data on the efficacy and safety of treatments,
 - the work on data quality & labelling and EU representativeness,
 - the development of common minimal datasets.
- **To reinforce international collaboration on post-launch evidence generation (PLEG) studies, in particular between regulators and HTA bodies.** Take the opportunity of the entry in force of the HTA regulation in January 2025 to increase voluntary cooperation within the EU, discuss respective needs and available data sources at an early stage, to improve efficiency.